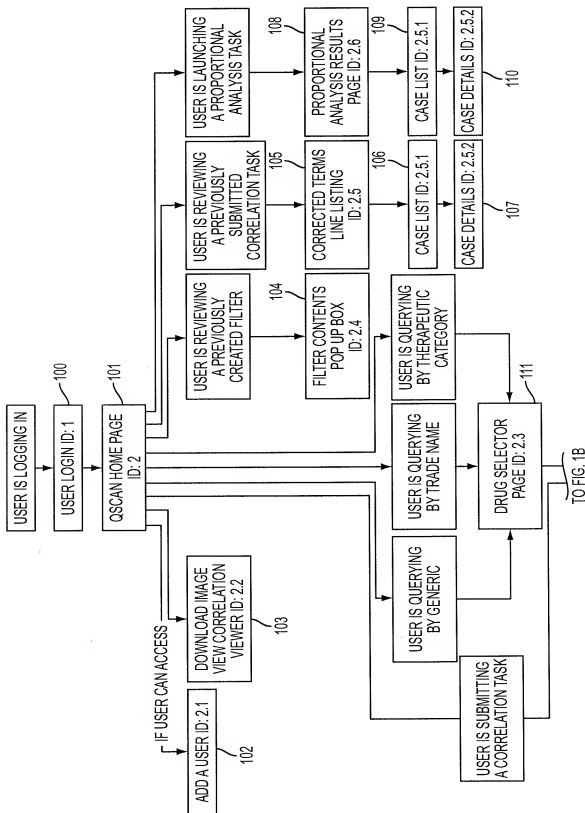


REPLACEMENT SHEET



TO FIG. 1B

FIG. 1A

REPLACEMENT SHEET

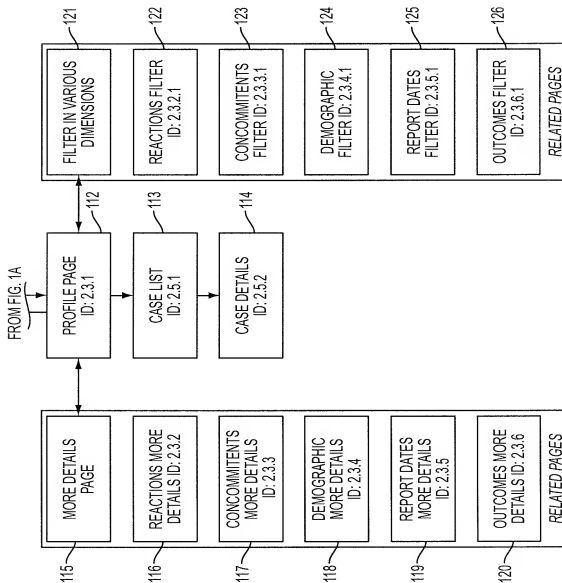


FIG. 1B

REPLACEMENT SHEET

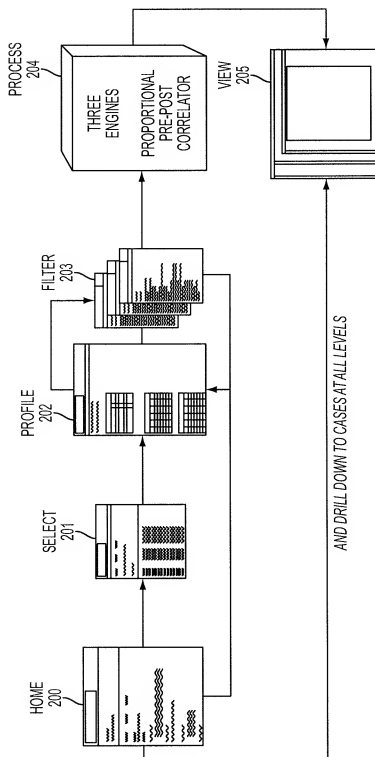


FIG. 2

REPLACEMENT SHEET

QSCAN **Pharmacovigilance
Selector/Profiler**

home

Selector/Profiler: Data source: FDA SRS/AERS, Combined Data

Generic Name:

Trade Name:

Therapeutic category:

Search

Search

Ace Inhibitors

Search

Filtering:

Saved filter:

Select...

View

Apply

AEM Engine notices:

• [delete] [Dec. 22, 2000 6:41:42 PM] Completed correlation task #15 AMLODIPINE BESYLATE view results...

• [delete] [Dec. 22, 2000 6:25:17 PM] Completed correlation task #14 CANDESARTAN CILEXETIL view results...

Proportional analysis:

Compute for therapeutic category:

Ace inhibitors

Go

☒ Bayesian filtering

☐ Compare only with therapeutic category

Administrative tasks:

• Add New User

• Log out

• Download the ImageView 1.1.4.1 Correlation viewer (1.3 MB)

FIG. 3

REPLACEMENT SHEET

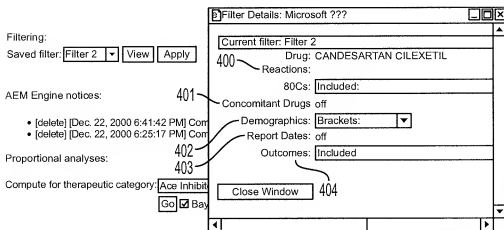


FIG. 4

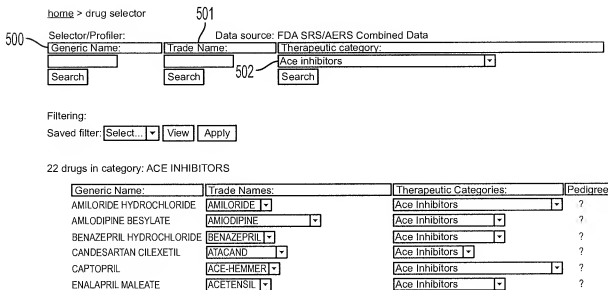


FIG. 5

REPLACEMENT SHEET

Merge Filter

✓ Reactions | Drugs | Outcomes | Report Sources | Timeframes | Demographics | Cases | Filter Notes |

deafness

Find Term

Reactions

☒ blood and lymphatic system disorders

☒ cardiac disorders

☒ congenital and familial/genetic disorders

☒ ear and labyrinth disorders

☒ external ear disorders (exc congenital)

☒ hearing disorders

☒ deafness and hyperacusis

☐ deafness conductive (exc otosclerosis)

☐ deafness neurosensory

☐ deafness permanent

☒ deafness transitory

☒ dysacusis

☒ hearing impaired

☐ hearing impairment aggravated

☐ hyperacusis

☒ hypoacusis

☐ presbycusis

☒ inner ear and vllith cranial nerve disorders

☒ middle ear disorders (exc congenital)

☒ miscellaneous ear disorders

☒ endocrine disorders

☒ eye disorders

☒ gastrointestinal disorders

Apply

Generate profile for this filter (This filter has not been profiled)

Save

FIG. 12

REPLACEMENT SHEET

Below are the top 200 correlated terms for your analysis on CANDESARTAN CILEXETIL (Task 95) View with Image/View

Correlated Terms					
[Rank]	[Score]	[Term 1]	[Category]	[Term 2]	[Category]
1	7706	Female	Sex	CANDESARTAN CILEXETIL	Target Drug
2	7661	Renal Function Analysis	Other Reaction	Renal failure and impairment	Other Reaction
3	7244	Paralysis (exc congenital and cranial nerve)	Other Reaction	Central nervous system hemorrhages and cerebrovascular accidents	Other Reaction
4	6901	HOS	Outcome	CANDESARTAN CILEXETIL	Target Drug
5	6888	TRIAMTERENE	Other Drug	DICLOFENAC SODIUM	Other Drug
6	6286	OTH	Outcome	CANDESARTAN CILEXETIL	Target Drug
7	5868	Sex Not Specified	Sex	Age Not Specified	Age
8	5773	VERAPAMIL	Other Drug	TRIAMTERENE	Other Drug
9	5765	HOS	Outcome	Female	Sex
10	5753	Male	Sex	CANDESARTAN CILEXETIL	Target Drug

FIG. 13

REPLACEMENT SHEET

Correlation Details

Analyzed Drug: CANDESARTAN CILEXETIL

Cases for term pair: Renal function analyses [Other Reaction] / Renal failure and impairment [Other Reaction]

Cases 1 to 18 of 18 cases

Case ID	Sex	Manufacturer Control Code	FDA Report Receipt Date	Age	Drugs	Reactions	Serious
1 3263641	F	19990300088	1999-06-17	74	Atacand	Blood Creatinine Increased; Dialysis Nos; Renal Failure Aggravated	N
2 3198047	F	19990200143	1999-03-12	57	Acuretic, Atrovastatin, Atacand, Cefixime, Nitro-Dur, Terbasmin Expectorante	Blood Creatinine Increased; Blood Urea Increased; Hypotension NOS; Renal Failure Acute	Y
3 3171644	F	19981100002	1999-01-17	69	Xanax, Acetylsalicylic Acid, Wellbutrin, Atacand, Arthrotec, Digoxin, Levaquin, Claritin, Antivert, Pyridium, Zolof, Dyazide, Verapamil-Slow Release, Ambien	Abdominal Pain Nos; Blood Creatinine Increased; Blood Urea Increased; Coronary Artery Disease Nos; Haemoptysis; Heart Rate Increased; Hypertension Aggravated; Renal Failure Acute	N
4 3270258	F	19990400499	1999-06-26	75	Atacand, Hydrochlorothiazide	Atrioventricular Blood Second Degree; Blood Creatinine Increased; Blood Pressure Decreased; Electrocardiogram ST Segment Depression; Electrocardiogram U Wave Appearance; Electrolyte Imbalance Hypochloreaemia; Hypokalaemia; Hyponatraemia; Loss of Consciousness Nec; Renal Impairment Nos; Syncope	N

FIG. 14

REPLACEMENT SHEET

Correlation Details

Analyzed Drug: CANDESARTAN CILEXETIL

Case for term pair: Renal function analyses [Other Reaction] / Renal failure and impairment [Other Reaction]

1501	Case ID:	3198047				
1502	Sex:	F				
1503	Age:	57.0 years, 0.0 months				
	Reactions:	As Reported	Preferred Term	High Level Term	High Level Group Term	System Organ Class
		Blood Creatinine Increased	Blood Creatinine Increased	Renal Function analysis	Renal and urinary tract investigations and urinalysis	Investigations
1504		Blood Urea Increased	Blood Urea Increased	Renal Function analysis	Renal and urinary tract investigations and urinalysis	Investigations
		Hypotension NOS	Hypotension NOS	Hypotension	Decreased and non-specific blood pressure disorders and shock	Vascular disorders
		Renal Failure Acute	Renal Failure Acute	Renal failure and impairment	Renal disorders (exc nephropathies)	Renal and urinary disorders
	Concomitant Drugs:	Name	Dose	Route	Suspect Status	
		Acuretic	TAB QD		Yes	
1505		Atorvastatin			No	
		Atacand	16 MG QD PO ORAL		Yes	
		Cefixime			No	
		Nitro-Dur			No	
		Terbasmin Expectorante			No	
1506	Outcomes:	HOSPITALIZATION-INITIAL OR PROLONGED (HO) LIFE-THREATENING (LT)				
1507	Manufacturer Control Code:	19990200143				
1508	Manufacturer Date:	1999-03-5				
1509	Adverse Event Date:	1998-12-13				
1510	Report Type:	EXP				
1511	Report Source:	OTH				
1512	Case Source:	AERS				
1513	Narrative:					

FIG. 15

REPLACEMENT SHEET

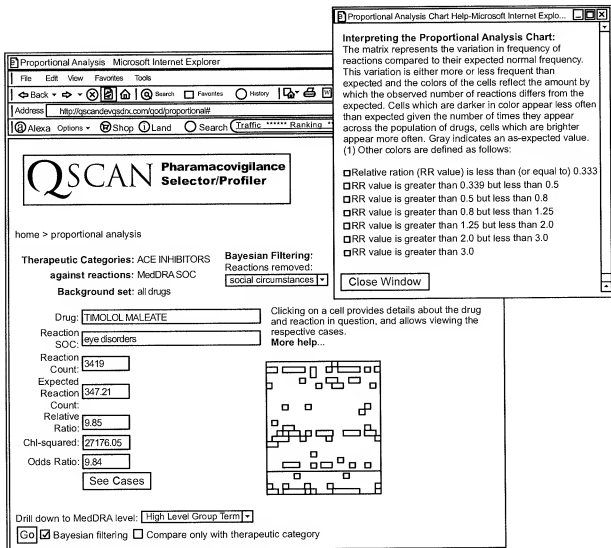


FIG. 17

REPLACEMENT SHEET

Proportional Analysis
 [ACE INHIBITORS] vs. Reactions (SOCs)
 View by HLGTS

1800 — Drug:

1801 — Reaction:

1802 — Reaction Count:

1803 — Expected Reaction Count:

1804 — Relative Ratio:

FIG. 18

550 entries for this analysis are displayed below.

Correlated Terms		1900	1901	1902	1903	1904
	[Reaction]	[Drug]	[Count]	Expected Count]	[Relative Ratio]	
1	6: Eye disorders	19: TIMOLOL MALEATE	3392	346.3	9.8	
2	24: Surgical and medical procedures	2: AMLODIPINE BESYLATE	1732	200.4	8.6	
3	14: Metabolism and nutrition disorders	1: AMILORIDE HYDROCHLORIDE	838	266.5	3.1	
4	24: Surgical and medical procedures	13: METHYLDOPA	37	15.6	2.4	
5	16: Neoplasms benign and malignant (including cysts and polyps)	17: RESERPINE	65	28.6	2.3	
6	4: Ear and labyrinth disorders	4: CANDESARTAN CILEXETIL	32	14.3	2.2	
7	24: Surgical and medical procedures	20: TRANDOLAPRIL	13	6	2.2	
8	14: Metabolism and nutrition disorders	18: SPIRONOLACTONE	1330	616.1	2.2	

FIG. 19

REPLACEMENT SHEET

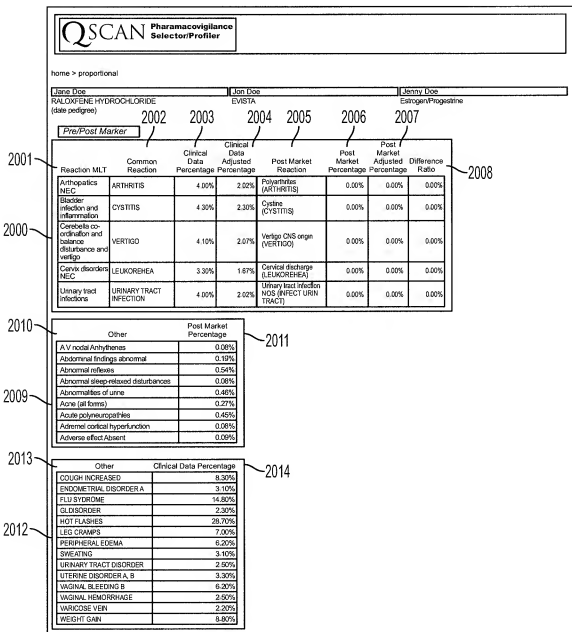


FIG. 20

REPLACEMENT SHEET

home > drug selector > drug profile > case list

Drug: BENAZEPRIL HYDROCHLORIDE

Reactions: SOCs:

Concomitant Drugs: off

Demographics: off

Report Dates: off

Outcomes: off

Summary view... Cases 1 to 50 of 268 cases

6 pages:

1 51 101 151 201 251

	2100	2101	2102	2103	2104	2105	2106	2107
	[Case ID]	[Sex]	[Manufacturer Control Code]	[FDA Report Receipt Date]	[Age]	Drugs	Reactions	[Serious]
1	3510123	F	200010174BBE	2000-06-1		Tylenol, Albuterol, Duruluss G Pm, Aspirin, Asulfemethoxzo Ex Bid, Astelin, Lotansin, Zyrtec, Doxerex, Benadryl, Premarin, Lasix, Hoz 25 Mg, Hydrocodone, Immune Globulin Intravenous (Human), Ganimmune N 10% - Placeto, Iodine, Xyllocaine, Claritin, Glucophage, Methylprednisolone, Nasonex, Singulair, Prilosec, Oxygen, Paxil, Solumadrol Pack, Rezulin 200 Mg Am	Cardiac Murmur Nos; Dyspepsia, Dyspnoea Nos; Oedema Lower Limb; Pain in Limb; Phlebitis Nos; Physical Examination Nos Abnormal; Rhinorrhea; Tenderness Nos; Venous Thrombosis Deep Limb	Y
2	C01979033	F	97USA10651	1997-09-8		LOTENSIN	Hypertension NOS, Tablet in stool	N
3	3204365	F	98061673	1998-08-26		Aspirin Coated, Lotensin, Niaspan	Asthenia, Dizziness (Exc Vertigo), Dyspepsia, Flushing, Pain Nos	Y
4	C01455473	F	933544001	1994-05-28		LOTENSIN	Nausea, Vasodilation	N

FIG. 21